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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/849,525	08/29/1997	GHITA LANZENDORFER	435-WCG	3976

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/849,525	LANZENDORFER ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-36* is/are pending in the application.

4a) Of the above claim(s) *25-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on May 10, 2005 has been entered. Claims 19-36 are pending. Claims 25-34 stand withdrawn. Claims 19-24, 35-36 are now under consideration.

Newly submitted claim 35-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: compositions comprising a flavonoid has long been known in the art. Accordingly, they are not viewed to be a new contribution to the art. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-25 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP 821.03.

Double Patenting

2. Claims 19-24 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,952,373, claims 1-5 of US Patent 6,121,243 and claims 1-2 of US patent 6,562,794.

Per Applicant's request in the Amendment, filed on May 10, 2005, the double patenting rejections is held in abeyance until allowable subject matter is indicated.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites formulations comprising an effective amount therefore of a cosmetic or dermatologic use comprising one or more flavanoids as recited in lines 2-6 of the claim, which is a broad range for the concentration of claimed flavonoids. The claim further contains limitations wherein the element (a) of the formulation, namely the flavonoids, comprise in 0.001 % to 30% by weight, which is a narrower range of the limitation "cosmetic or dermatologically effective amounts". Accordingly, the claim appears to contain a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim). Such recitations are considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989). The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al US Patent 5,145,781 in view of Middleton et al (Middleton) (Middleton and Chithan, *The Flavonoids, Advances in Research Since 1986*, 1994, Chapman & Hill, London, Ch. 15, pp 619-645, already on record), Harrrison's (*Harrison's Principles of Internal Medicine*, 1994, New York, McGraw-Hill, Inc., 13th edition, pp. 309-313, already on record).

The instant claims are directed to methods of using cosmetic or dermatological formulations comprising flavonoids such as alpha glucosyl rutin, optionally one or more cinnamic acid derivatives and optionally an antioxidant. The instant immunosuppression encompass any type of biological effects that cause attenuation of immune system.

Applicant is informed that during patent examination, the pending claims are given the broadest reasonable interpretation consistent with the specification. Accordingly, the recitation of "optionally" does not limit the instant formulations to the recited optional component.

Suzuki et al disclose α-glycosyl rutin which is a flavonoid encompassed by the instant claims. Suzuki discloses various uses of α-glycosyl rutin (col 8, lines 45-56; col 10, lines 4-30). Suzuki discloses cosmetic compositions comprising α-glycosyl rutin in amounts of about 1-10 W/V %(see col 5, lines 55-59; col 19-20, col 20, lines 30-41). Suzuki specifically discloses the use of such rutin as UV absorbant. (col 8, lines 45-55, col 22, lines 45-67). Suzuki teaches the use of his compositions for immune conditions

such as malignant tumors. Suzuki also teaches the incorporation of antioxidants. (see col 21, lines 1-25). Suzuki meets all elements of the instant claims except its use for immunosuppression of skin cells induced by UVB radiation.

Middleton is merely used to show the plethora of information about the effects of flavonoids on immune system (pp 619-620). Accordingly, it is well within purview of an ordinary skill to modulate the activity of immune system by administering flavonoids of interest (Ch. 15, pp 619-645). For example, genistein have been shown to inhibit T-lymphocyte activity by inhibiting protein tyrosine kinase (see pp 625, 2nd col, 1st paragraph). Quercetin has been effective in regressing the spread of fibrosarcoma in vitro (see pp 627, 2nd col). Similarly, flavonal glycosides such as mauritanin and myricitrin have been shown to improve the delayed-type hypersensitivity among mice undergoing two-stage carcinogenesis (see top of pp 628).

Moreover, like alpha glucosyl rutin, topical quercetin has been effective in preventing and improving various immunosuppressive conditions associated with skin cancer (see pp 642, 3rd -8th paragraphs). Therefore, the general knowledge available in the art provides for the beneficial effects of topical flavonoids in improving immunosupresseive conditions regardless of their etiology.

Harisson's is used to show the general knowledge in the art about the etiology of solar radiation and systemic immune response caused by UV-B exposure (see pp 309 last paragraph). Accordingly, the immunesuppression caused by UV-B is caused by the induction of suppressor T cells throughout the body.

Middleton and Harisson's collectively teach the general knowledge of an ordinary skill in the art of medicine and immunology about the beneficial effects of flavonoids on immune system; and the etiology of immunosuprression cause by UV-B.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to apply Suzuki's formulations topically to modulate immune suppressions caused by UV-B exposure, because as taught Harrison's, such immunosuprression is dependent on the activity of T-lymphocyte which as taught by Middleton, can be controlled by topical administration of a flavonoid of choice.

Thus, one of ordinary skill in the art understanding the etiology of UV-B induced skin conditions would have had a reasonable expecatiaotn of success in applying Suzuki's formulations for its immunologic effects because as taught by Middleton, the ordinary skill in the art would have had a reasonable expectation of success for its beneficial immune effects.

Moreover, the instant method claims 19 and 25 are not limited to any specific etiology associated with UV-B induced immunesuppression; rather, said claims are limited to the recitation of a single method steps, wherein the method comprise applying to the skin of a person an effective amount of one or more flavonoids, as recited in the body of the claim. Accordingly, the instant claims are *prima facia* obvious, because the ordinary skill in the art would have known of various beneficial effects of flavonoids on immune system when using Suzuki's compositions topically.

Response to Arguments

5. Applicant's arguments filed May 10, 2005 have been fully considered but they are not persuasive.

Applicant argues that the references do not teach the instantly claimed concentrations.

In response Examiner states that contrary to Applicant's position, Suzuki clearly teaches cosmetically or dermatilogically effective amounts of β-glycosyl rutin at numerous places in his formulation (see col 17-col 20). Accordingly, the combined teachings of references meet all elements of the instant claims.

Conclusion

6. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER